UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/722,659	09/27/1996	D. CLARK BENNETT	104385.140	4359

7590 01/13/2003

HOLLIE L. BAKER
HALE & DORR LLP.
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
DECLOUX, AMY M	

ART UNIT	PAPER NUMBER
1644	46

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 46

Application Number: 08/722,659
Filing Date: September 27, 1996
Appellant(s): BENNETT ET AL.

Maria L. Maebius
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11-4-02 (Paper No. 44).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellants state that Claims 1-7 and 18-19 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,997,863	Zimmerman	12-1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7 and 18-19 are rejected under 35 U.S.C. 102(e) or (f) as being anticipated by U.S. Patent No. 5,997,863, filed 7-8-1994. The inventive entity of U.S. Patent 5, 997,863 has inventors in common with the instant application, but is not the same inventive entity as that of the instant application. The applied reference has a common inventor with the instant application. Based on the earlier effective US filing date of the reference, it constitutes prior art under 102(e). This rejection under 102(e) might be overcome either by showing under 37 CFR 1.132 that any invention of this invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another" or an appropriate showing under CFR 1.131.

The '863 patent teaches a method of treating ischemia in a rabbit hind limb ischemic model by administering heparinase 1 (see column 8, lines 62 through claim 18, line 34, in particular). The '863 patent also discloses that administering heparinase releases heparin binding growth factors and degrading components of the extracellular matrix, thereby facilitating the mobility of cytokines, chemoattractants and cells (see column 6, lines 25-59, in particular). The '863 patent further discloses that wound healing is generally divided into three temporally overlapping phases, inflammation, proliferation and remodeling. During inflammation, blood borne cells infiltrate the wound site and release mediating factors (see column 2, lines 56-67, in particular. The instant specification on page 39 teaches that ischemia induces inflammatory response such as migration of neutrophils across the connective tissue , extravasation of plasma and other blood and cellular components. Therefore, the method of treating ischemia by administering heparinase taught by the '863 patent would also decrease the localized

inflammatory responses that result from ischemia. Thus, the methods of the '863 patent anticipate the instantly claimed method of decreasing localized inflammatory responses.

(11) Response to Argument

The papers labeled Appendixes C-G, which are attached to the instant Appeal Brief, will not be considered because there is no showing of good and sufficient reasons why they were not presented earlier. See §1.195 which states "Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented."

Appellant states that with respect to the rejection under 102(f), the office actions do not elucidate the positions taken with this rejection (page 7, lines 6-7). The Examiner points out that the Office Action mailed 12-18-01 (Paper No. 36) does elucidate the positions taken with this rejection. Specifically, page 2 of Paper No. 22 states that "The inventive entity of U.S. Patent No. 5,997,863 has inventors in common with the instant application but is not the same inventive entity as that of the instant application".

Appellant states that with respect to the rejection under 102(f), that MPEP 706.02(g) states that the examiner must presume the appellants are the proper inventors unless there is proof that another made the invention and that appellant derived the invention from the true invention. It is noted that as of this date, no object evidence has been presented that validates Appellant's contention that the inventive identities are not identical. It is noted by the Examiner that there are several inventors of the instant application that are not listed as inventors of the '863 patent.

Appellant contends that because '863 fails to expressly or inherently disclose each of the elements recited in claims 1-7 and 18-19, '863 is not anticipatory. Sections A-D, pages 8-14 of the instant Brief, address Appellant's contentions that '863 does not teach that ischemia induces an inflammatory response and that '863 does not teach that intravascular administration of heparinase results in a reduced localized inflammatory response arising from an ischemia/reperfusion injury by decreasing neutrophil transmigration through activated endothelium and basement membrane of the vasculature, (page 8, lines 6-10).

In Section A Appellant contends that '863 teaches heparinase enhanced neutrophil transmigration which is contrary to the claimed invention. Appellant refers to a review article by Singer and Smith attached to the instant brief, which as discussed supra, is not being considered presently. Appellant states that '863 states that heparinase increases the mobility of cells through the extracellular matrix (last 3 lines of page 8 and lines 1-2 of page 9 of the instant Brief). However the Examiner notes that '863 does not specifically teach that heparinase enhances neutrophil transmigration, but only suggests that transmigration of cells through the extracellular matrix is enhanced by the administration of heparinase, as acknowledged by Appellant in the instant Brief, (page 9, lines 2-4). Therefore, it is the Examiner's position that '863 does not

specifically teach heparinase enhanced neutrophil transmigration, and thus is not contrary to the claimed invention.

In Section B Appellant contends that wound healing as described by '863 cannot be equated to reducing inflammation. Appellant states that '863 teaches that wound healing involves at least three different phases: inflammation, proliferation and remodeling and that '863 is directed to enhanced wound healing by administration of heparinase, with which the Examiner agrees. Appellant contends that enhanced wound healing by administration of heparinase, taught by '863, requires that inflammation be a step in the wound healing process, with which the Ezaminer does not disagree. However the examiner does not see from this, how Appellant concludes that "therefore, unlike the claimed invention, '863 does not teach reducing inflammation". It is the Examiner's position, that just because wound healing requires some inflammation, Appellant has not determined that the administration of heparinase does not reduce inflammation, as recited in the instant claims, as long as a minimum amount of inflammation required for wound healing to occur is present.

Appellant further concludes in said section B of the Brief, that accordingly '863 does not teach a method of reducing a localized inflammatory response as recited in the instant claims. That '863 does teach a localized response is evidenced by the heading of Example 8 in '863 which is entitled "Evaluation of the Local Administration of Heparinase to Enhance Revascularization", thus indicating a localized treatment for a localized response, and also by the teaching that the administration of heparinase intravascularly could be used as a treatment of vessels in ischemic regions (column 13, paragraph 4 of '863), as noted on page 3 of the office action filed 8-1-00 (Paper No. 22). Though '863 does not appear to teach that its method of wound healing explicitly contains the limitation reduces inflammation, such a limitation would be inherent, absent evidence to the contrary.

In Section C Appellant contends that the examiner impermissibly relies on the Appellant's own specification to teach that ischemia causes a localized inflammatory response, and that Appellant's own specification can not be applied as prior art under 102. However, appellant's own specification's teaching that ischemia induces inflammatory responses such as migration of neutrophils across the connective tissues, was not claimed by Appellant to be Appellant's discovery, and appears to be known in the art at the time the invention was made. Appellant contends that '863 does not describe the reduction of localized inflammation, and focuses on the effects of heparinase to enhance wound healing, and emphasizes the modulation of tissue formation and revascularization, not inflammation. However, since ischemia causes a localized inflammatory response as discussed above, one of ordinary skill in the art could not say when the administration of heparinase taught by '863 ceased being a treatment for ischemia/reperfusion injury and began being a treatment for wound healing.

In Section D Appellant contends that the mechanism addressed in the claimed invention is distinct from that described in '863. However, a mechanism of action of an administered substance is not given patentable weight. And, as discussed above, the instant claimed limitation of reducing the transmigration of neutrophils by the administration of heparinase, is

not inconsistent with '863's teaching of a method of administering heparinase for enhancing wound healing, wherein wound healing comprises inflammation, as discussed above, since the instant claims do not teach the absence of inflammation, only its reduction. Appellant then presents an argument against inherency based on newly presented material attached to the instant Brief as Appendix G. Since said material is not being considered as discussed supra, the examiner will not address this portion of the Brief.

In Section E Appellant contends that the rejection under 102 (f) is improper because the instant application and '863 are directed to two different inventions. However, the Examiner disagrees with this contention, for the reasons discussed supra.

In Section F, Appellant contends that '863 can not be applied under 35 USC 103 because '863 was commonly assigned to Ibex Technologies R and D, Inc., and was subsequently assigned together to BioMarin Enzymes, Inc. However there is no outstanding obviousness rejection applied to the instant claims currently.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Amy DeCloux, Ph.D.
January 13, 2003

Conferees
Christina Chan
SPE, Art Unit 1644
Anthony Caputa, Ph.D.
SPE, Art Unit 1642

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

HOLLIE L. BAKER
HALE & DORR LLP.
60 STATE STREET
BOSTON, MA 02109